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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,129	08/22/2003	Todd Bucciarelli	MBHB04-101-C	8860

7590 11/02/2005
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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,129

Applicant(s)

BUCCIARELLI ET AL.

Examiner

Michail A. Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 43-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-42 and 57-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-62 are pending.

2. Applicant's election of Group III, claims 31-42 and 57-62, and p21 as specific member of Cip/Kip family and p16 as specific member of INK family and SEQ ID NO:13 as a specific Cy motif in the reply filed on 09/08/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further consideration, the prior art search has been extended to include all species of Cip/Kip family, and all species of INK4 family, recited in claims 41 and 42 and all Cy motif, as recited in claim 59. The species election is hereby withdrawn.

Claims 1-30, 43-56 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 31-42 and 57-62, drawn to an expression vector comprising a minimal promoter comprising TATA sequence and two phase tetracycline operators downstream from TATA sequence and two phased tetracycline operators downstream from TATA sequence are under consideration in the instant application.

3. The specification on page 1, line 4 should be amended to reflect the status of the parent 09/935,194 application..

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

5. Claim 60 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim. See MPEP § 608.01(n).

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 31-42 and 57-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 31-42 and 57-62 are indefinite and ambiguous in the recitation of “two phased tetracycline operators”. The metes and bounds of the phrase “two phased tetracycline operators” is unclear. It might mean one operator working in two-phase mode or two operators. Applicant is invited to clarify whether there are one or two operators and show the support within the specification as filed.

9. Claim 32 and 34 are indefinite and ambiguous in the recitation of “two phases tetracycline operators downstream from the TATA sequence are 21 basepairs downstream from the TATA sequence”. If the claimed expression vector comprises **two** tetracycline operators that both located downstream from the TATA sequence, then it is unclear how each of the two operators can be located 21 basepairs downstream from the TATA sequence ?

9. Claim 33 and 34 are indefinite and ambiguous in the recitation of “two phases tetracycline operators upstream from the TATA sequence are 11 basepairs upstream from the TATA sequence”. If the claimed expression vector comprises **two** tetracycline operators that both located upstream from the TATA sequence, then it is unclear how each of the two operators can be located 11 basepairs upstream from the TATA sequence ?

10. Claim 42 is indefinite and ambiguous in the recitation of “wherein the vector encodes more than one cyclin-dependent kinase...”. The base claim 39 recites a vector comprising **a gene** that encodes **a cyclin dependent kinase inhibitor**. In other words, the claimed vector encoded only one cyclin-dependent kinase inhibitor. It is unclear how said vector, comprising only one specific gene can encode more than one cyclin-dependent kinase inhibitors?

11. Claim 57-62 are indefinite and ambiguous in the recitation of “wherein the expression vector encodes one or a multiplicity of Cy motifs”. The base claim 31 recites a vector comprising **a gene**. In other words, the claimed vector encoded only one cyclin-dependent kinase inhibitor. It is unclear how said vector, comprising only one specific gene can encode a multiplicity of Cy motifs?

Art Unit: 1644

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 57-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“ The expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Cy motifs having an amino acid sequence (Lys/Arg)-Xaa-Leu” claimed in claims 57-59; “ the expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Ankyrin repeat motifs” claimed in claims 61 and 62 represent(s) a departure from the specification and the claims as originally filed and applicant has not pointed out where the support come(s) from. The specification and the claims as originally filed only support “The expression vector of claim 31, wherein the expression vector encodes cyclin-dependent kinase inhibitors selected from the group recited in claims 41 and 42.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
October 28, 2005

